Form PTO-1082

Docket No.: PAT-1129

Date: February 7, 1997

Box Patent Applications
Commissioner of Patents & Trademarks
Washington, D.C. 20231

Dear Sir:

Transmitted herewith for filing is the patent application of:

INVENTOR(S): GARY S. ROUBIN, GEOFFREY H. WHITE, SRIAN IYER, RUSSELL J. REDMOND, CLAUDE A. VIDAL

FOR: NON-FORESHORTENING INTRALUMINAL PROSTHESIS

Enclosed are:

(X) SIX sheets of formal drawings

(X) Declaration and Power of Attorney will follow.

(X) An assignment of the invention to Cornerstone Devices, Inc. will follow.

( ) A certified copy of _____ from which priority is claimed in the subject case pursuant to Rule 55(b) and 35 USC 119. _____ Will Follow.

(X) One Verified Statement to establish small entity status under 37 CFR 1.9 and 37 CFR 1.27 will follow.

( ) Information Disclosure Statement; ___ sheets of Form PTO-1449; and copies of listed references.

	Number Filed	Number Extra	Rate	Large Entity Fee	Rate	Small Entity Fee
Basic Fee				$____		$385
Total Claims	32	- 20 = 12	x $22 =	____	x $11 =	132
Indep. Claims	3	- 3 = 0	x $80 =	____	x $40 =	0
Multiple Dependent Claims			+ $260 =	____	+ $130=	0
			TOTAL =	$____		$517.00

(X) A check in the amount of $517.00 to cover the filing fee will be forwarded with the Declaration and Verified Statement.

( ) A check for $___ covering the Recordation of Assignment fee is enclosed.

Respectfully Submitted,

RAYMOND SUN, Reg. No. 35,699
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PAT-1129

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of)
)
ROUBIN et al.)
)
Serial No.: 08/797,814)
)
Filing Date: February 7, 1997)
)
For: NON-FORESHORTENING)
INTRALUMINAL PROSTHESIS)
)

Art Unit: 3309

Examiner: Not Known

Honorable Commissioner Of
Patents And Trademarks
Washington, DC 20231

PETITION FOR EXTENSION OF TIME

Dear Sir:

Pursuant to 37 C.F.R. 1.136(a), an extension of time of one (1) month is hereby requested to respond to the Notice to File Missing Parts mailed March 19, 1997. The small entity fee of $55.00 pursuant to 37 C.F.R. 1.17(a) is enclosed herewith.

Respectfully submitted,

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Dated: June 12, 1997

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on the date below.

Raymond Sun
Reg. No. 35,699

June 12, 1997
(Date)

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Docket: PAT-1129

U.S. PATENT APPLICATION

FOR

NON-FORESHORTENING INTRALUMINAL PROSTHESIS

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NON-FORESHORTENING INTRALUMINAL PROSTHESIS

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to an intraluminal prosthesis for implantation into a mammalian vessel, and in particular, to an intraluminal stent that is delivered in a compressed state to a specific location inside the lumen of a mammalian vessel and then deployed to an expanded state to support the vessel. The intraluminal stent is provided with a structural configuration that maintains the prosthesis at substantially the same length in both the compressed and expanded states. The intraluminal stent may also be provided with varying rigidity or flexibility along its length.

2. Description of the Prior Art

Intraluminal prosthesis, such as stents, are commonly used in the repair of aneurysms, as liners for vessels, or to provide mechanical support to prevent the collapse of stenosed or occluded vessels. These stents are typically delivered in a compressed state to a specific location inside the lumen of a vessel or other tubular structures, and then deployed at that location of the lumen to an expanded state. The stent has a diameter in its expanded state which is several times larger than the diameter of the stent in its compressed state. These stents are also frequently deployed in the treatment of atherosclerotic stenosis in blood vessels, especially after percutaneous transluminal coronary angioplasty (PTCA) procedures, to improve the results of the procedure and to reduce the likelihood of restenosis.

The positioning of a stent at the desired location in the lumen of a body vessel is a critical factor that affects the performance of the stent and the success of the medical procedure. Since the region in a lumen at which the stent is to be deployed is usually very difficult for a physician to

access, it is essential that the stent's deployed diameter and length be known before the physician can accurately position a stent with the correct size at the precise location. For example, since the diameter and the length of the diseased or damaged segment or region of the body vessel can vary for different body vessels, disease states, and deployment purposes, it is important that a stent having the precise diameter and length be delivered to this region for deployment.

Careful sizing of this region of the lumen of the body vessel may pose a difficult challenge for many physicians who know the exact dimensions of the body vessel at this region, but are not certain about the stent's deployed diameter and length. This is due to a foreshortening effect which is experienced by many stents when they are expanded from their compressed state to their expanded state.

This foreshortening effect is illustrated in FIGS. 1A, 1B, 2A and 2B, which illustrate portions 20 of a stent having a mesh-like pattern made up of V-shaped struts or legs 22 and 24 connected at their apices 26. Two pairs of these V-shaped struts 22, 24 are illustrated in this portion 20 of the stent. Each of these struts 22 and 24 has a length h. FIG. 1B illustrates the portion 20 of the stent in a fully compressed state, in which the length h has a longitudinal or horizontal component l_2 (see FIG. 2B), and FIG. 1A illustrates the same portion 20 of the stent in a fully expanded state, in which the length h has a longitudinal or horizontal component l_1 (see FIG. 2A). As illustrated by the imaginary lines 28 and 30 in FIGS. 1A and 1B, and in FIGS. 2A and 2B, l_1 is shorter than l_2 because the angle which the strut 22 assumes with respect to the horizontal axis is greater when in the expanded state, so the length of the expanded portion 20 is shorter than the length of the compressed portion 20 by a length of 2d. This foreshortening is caused by the shortening of the longitudinal component l of the struts 22 and 24 as the stent is expanded from the compressed state to the expanded state.

This foreshortening effect is troublesome because it is not easy to determine the exact dimension of this foreshortened length 2d. The physician must make this calculation based on the material of the stent, the body vessel being treated, and the expected diameter of the stent when properly deployed in the lumen of the body vessel. For example, the foreshortened length 2d will vary when the same stent is deployed in vessels having different diameters at the region of deployment.

In addition, there are certain body vessels that experience a change in vessel lumen diameter, anatomy or disease state along their lengths. Stents to be deployed at such vessels will need to be capable of addressing or adapting to these changes.

An example of such a body vessel are the carotid arteries. Blood is delivered from the heart to the head via the common carotid arteries. These arteries are approximately 8-10 mm in lumen diameter as they make their way along the neck up to a position just below and behind the ear. At this point, the common carotid artery branches into a 6-8 mm lumen diameter internal carotid artery, which feeds blood to the brain, and a 6-8 mm lumen diameter external carotid artery, which supplies blood to the face and scalp. Atherosclerotic lesions of the carotid artery tend to occur around this bifurcation of the common carotid artery into the internal and external carotid arteries, so stents often need to be deployed at this bifurcation.

Another example are the iliac arteries, which have a lumen diameter of about 8-10 mm at the common iliac artery but which decrease to a lumen diameter of about 6-7 mm at the external iliac artery. The common iliac arteries experience more localized stenosis or occlusive lesion which are quite often calcific and usually require a shorter stent with greater radial strength or rigidity. More diffused atherosclerotic disease of the iliac system will commonly involve both the common and external iliac arteries, and necessitate a longer

stent having increased flexibility that is suitable for deployment in the tortuous angulation experienced by the iliac system.

The femoropopliteal system similarly experiences localized and diffused stenotic lesions. In addition, the flexibility of a stent is important where deployed at locations of vessels that are affected by movements of joints, such as the hip joint or the knee joint.

The renal arteries provide yet another useful example. The initial 1 cm or so at the orifice of a renal artery is often quite firmly narrowed due to atheroma and calcification, and is relatively straight, while the remainder of the length of the renal artery is relatively curved. As a result, a stent intended for implantation at the renal arteries should be relatively rigid for its first 1.5 cm or so, and then become more flexible and compliant.

Thus, there remains a need for an intraluminal prosthesis that maintains a consistent length in both its fully compressed and fully expanded states, and in all states between its fully compressed and fully expanded states. There also remains a need for a stent which can accomodate body vessels having varying lumen diameters, different anatomies, and different disease states.

SUMMARY OF THE DISCLOSURE

In order to accomplish the objects of the present invention, there is provided a stent having a plurality of annular elements. Each annular element has a compressed state and an expanded state, and has a longitudinal dimension which is smaller in the expanded state than in the compressed state. A plurality of connecting members connect adjacent annular elements, with the connecting members operating to compensate for the smaller longitudinal dimension of each annular element in the expanded state.

In one embodiment of the present invention, each annular element includes a plurality of struts and apices connected to form an annular configuration. The connecting members are connected to the apices of the adjacent annular elements. The plurality of struts of the annular elements include left and right struts, with each pair of left and right struts connected to each other at an apex. Each strut has a longitudinal dimension which is smaller when the annular element is in the expanded state than in the compressed state.

In one embodiment of the present invention, at least one of the annular elements may have a closed configuration such that the plurality of alternating struts and apices are connected to each other to form a closed annular element. In addition, it is also possible for at least one of the annular elements to assume an open configuration such that the plurality of alternating struts and apices are not connected at at least one location.

In a preferred embodiment of the present invention, the connecting members have a plurality of alternating segments. In one embodiment, the connecting members have a plurality of alternating curved segments defining alternating top and bottom curved apices. In another embodiment, the connecting members have a plurality of alternating curved and straight segments. In a further embodiment, the connecting members have a plurality of alternating and angled straight segments. The connecting members have a larger longitudinal dimension when each annular element is in the expanded state than in the compressed state to compensate for the smaller longitudinal dimension of the annular element in the expanded state.

The stent according to the present invention further includes a plurality of apertures defined by adjacent annular elements and connecting members. In one embodiment, it is possible for the apertures of different segments of the stent to have different sizes.

The stent according to the present invention further provides a plurality of segments, at least two of which have a different degree of flexibility. In one embodiment, the varying flexibility is accomplished by forming a plurality of gaps. These gaps may be formed by omitting one or more of the connecting members, or portions of connecting members, between adjacent annular elements, or by omitting one or more of the struts, or by omitting connecting members and struts. In another embodiment, the varying flexibility is accomplished by providing the apertures of different stent segments with different sizes.

The stent according to the present invention may further provide segments that assume different diameters when the stent is in its expanded state. The differing diameters may be accomplished by providing the stent in a tapered or a stepped configuration.

In a preferred embodiment according to the present invention, the stent is made from a shape memory alloy, such as Nitinol, although other materials such as stainless steel, tantalum, titanium, elgiloy, gold, platinum, or any other metal or alloy, or polymers or composites, having sufficient biocompatibility, rigidity, flexibility, radial strength, radiopacity and antithrombogenicity can be used for the stent material.

Thus, the stent according to the present invention maintains a consistent length in both its fully compressed and fully expanded states, and in all states between its fully compressed and fully expanded states. As a result, the stent according to the present invention facilitates accurate sizing and deployment, thereby simplifying, and possibly reducing the time needed for, the medical procedure. In addition, the stent according to the present invention provides varying flexibility and rigidity along its length and/or circumference, as well as varying diameters along different segments of the stent, thereby facilitating the treatment of body vessels having

varying lumen diameters, different anatomies and different disease states.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1A is a side elevational view of a portion of a prior art stent in its expanded state;

FIG. 1B is a side elevational view of the portion of FIG. 1A in its compressed state;

FIG. 2A illustrates the longitudinal component of a strut of the stent of FIGS. 1A and 1B when the stent is in its expanded state;

FIG. 2B illustrates the longitudinal component of a strut of the stent of FIGS. 1A and 1B when the stent is in its compressed state;

FIG. 3 is a perspective view of a stent according to the present invention;

FIG. 4A is a side elevational view of a portion of the stent of FIG. 3 in its expanded state;

FIG. 4B is a side elevational view of the portion of FIG. 4A in its compressed state;

FIG. 5A illustrates the longitudinal component of a strut and its connecting member of the stent of FIGS. 4A and 4B when the stent is in its expanded state;

FIG. 5B illustrates the longitudinal component of a strut and its connecting member of the stent of FIGS. 4A and 4B when the stent is in its compressed state;

FIG. 6A is a side elevational view of the stent of FIG. 3 in its expanded state;

FIG. 6B is a side elevational view of the stent of FIG. 6A in its compressed state;

FIGS. 7 and 8 illustrate alternative embodiments of the connecting member according to the present invention;

FIG. 9 is a side elevational view of a portion of the stent of FIG. 3 illustrating a modification thereto;

facilitate deployment in body vessels that require such varying flexibility or rigidity. The varying flexibility or rigidity can be accomplished by omitting connecting members 48 and struts 42, 44, or by not connecting one or more struts 32, 44 and/or connecting members 48, thereby creating "gaps" at one or more locations along the stent 40. These locations can be anywhere along the length and/or the circumference of the stent 40. In addition, varying degrees of flexibility in the stent 40 can be accomplished by varying the patterns of these gaps. A non-limiting example would be to provide a substantially spiral pattern of omitted struts 42, 44 and/or connecting members 48, such as illustrated in FIG. 9. The omitted struts 42, 44 and connecting members 48 are illustrated in FIG. 9 in phantom (i.e., the dotted lines) by the numerals 47 (for the struts 42, 44) and 49 (for the connecting members). For example, the omitted struts 47 assume a relatively spiral pattern along the length of the stent 40 from the top left corner of FIG. 9 to the bottom right corner of FIG. 9, and can extend around the circumference of the stent 40. Similarly, the omitted connecting members 49 assume a relatively spiral pattern along the length of the stent 40 from the bottom left corner of FIG. 9 to the top right corner of FIG. 9, and can extend around the circumference of the stent 40.

Other non-limiting alternatives include providing such gaps 49 at one or both ends of the stent 40 only, or at a central portion of the stent 40. Further non-limiting alternatives would be to increase the number of these gaps 47, 49 from one or both ends of the stent 40 towards the center of the stent 40, or to increase the number of these gaps 47, 49 from the center of the stent 40 towards one or both ends of the stent 40. It is also possible to omit only a portion of certain connecting members 48 and not the entire ones of these connecting members 48. A portion of the stent 40 having a larger number of gaps 47, 49 would have greater flexibility or reduced rigidity.

As a result of the omitted struts 47, it is possible that some of the annular elements that are made up of the alternating struts 42, 44 may be closed or constitute completely connected annular elements, while some of these annular elements will be open annular elements.

The varying flexibility or rigidity can also be accomplished by providing a structural configuration where the size of the open areas or apertures 78 (for example, see FIGS. 4A and 10) defined between the struts 42, 44 and the connecting members 48 is varied at different portions or segments of the stent 40, along the length and/or circumference of the stent 40. In a non-limiting embodiment, all the apertures 78 in one segment of the stent 40 have substantially the same first size, and all the apertures 78 in another segment of the stent 40 have substantially the same second size, the first and second sizes being different. Additional segments, each having apertures 78 with substantially the same size as the other apertures 78 in that segment but having a different size as the apertures 78 in other segments, can also be provided.

Varying the size of apertures 78 can be accomplished by varying the lengths of the struts 42, 44 and the connecting members 48. For example, a smaller aperture 78 can be provided by shortening the lengths of the struts 42, 44 and the connecting members 48 that define the particular open area 78. Portions of the stent 40 with smaller apertures 78 are more rigid and less flexible than portions of the stent 40 with larger apertures 78. This allows the stent 40 to be deployed in body vessels that require a stent to be more rigid at one end, and to be increasingly flexible from the rigid end. Examples of such body vessels include the renal and iliac arteries discussed above.

Varying the sizes of the apertures 78 also serves other important purposes. For example, providing smaller apertures 78 at the opposing ends of the stent 40 provides increased or closer coverage of the vessel wall, thereby improving support

of the diseased vessel wall and preventing fragments of the plaque from being dislodged as embolic debris. The dislodgement of debris can be dangerous in certain vessels, such as the carotid arteries, where dislodged debris can be carried to the brain, possibly resulting in a stroke. As another example, providing larger apertures 78 at central portions of the stent 40 provides wider open areas that may be important in preventing the obstruction of side branches of other body vessels. These wider open areas also allow the passage of guidewires, catheters, stents, grafts, and other deployment devices through the body of the stent 40 into these side branches.

The stent 40 can also be provided in a manner in which it assumes a constant diameter in its compressed state, but in which different portions of the stent 40 can assume different diameters when in their fully expanded states. Providing an expandable stent 40 with the capability of assuming different diameters at different portions is important where the stent 40 is used in certain body vessels or branches of body vessels where the lumen diameters may vary. Examples of such body vessels and branches include the carotid and iliac arteries discussed above, and the esophagus.

The varying stent diameter can be provided in a number of ways. A first non-limiting alternative is to provide a gradually tapered configuration of the stent 40a, as shown in FIG. 11A. A tapered configuration is best-suited for use in body vessels which experience a gradual narrowing. A second non-limiting alternative is to provide an abrupt transition, such as a stepped configuration, between two stent segments each having a relatively consistent, but different, diameter. The step can be for a step-up 40c, as shown in FIG. 11C, or for a step-down 40b, as shown in FIG. 11B. In addition, a stent 40 can be provided with several changes in diameter along its length to match specific anatomical requirements.

The tapering or transitioning of the stent configuration can be accomplished by pre-shaping, and can be enhanced by variations in (1) the thickness of the stent material, (2) the size of apertures 78, and (3) the gaps 47, 49.

In addition to the above, it will be appreciated by those skilled in the art that varying flexibility and rigidity can also be accomplished by varying the width or thickness of the stent material at certain locations along the length and/or circumference of the stent 40.

A number of materials can be used for both the stent 40 and its struts 42, 44 and connecting members 48, depending on its method of deployment. If used as a self-expanding stent, the stent 40 (including its struts 42, 44 and connecting members 48) is preferably made of a shape memory superelastic metal alloy such as Nitinol, which has the unusual property of "mechanical" memory and trainability. This alloy can be formed into a first predetermined shape above a transition temperature range. The alloy may be plastically deformed into a second shape below the transition temperature range, but the alloy will completely recover to its original (first predetermined) shape when raised back above the transition temperature range. The Nitinol preferably has a composition of about 50% nickel and about 50% titanium. The properties of shape memory alloys such as Nitinol and their use in stents have been well-documented in the literature, and reference can be made to the article by T.W. Duerig, A.R. Pelton and D. Stockel entitled "The Use of Superelasticity in Medicine", a copy of which is attached hereto and specifically incorporated into this specification by specific reference thereto as though fully set forth herein.

Alternatively, the stent 40 (including its struts 42, 44 and connecting members 48) can be made of stainless steel, tantalum, titanium, elgiloy, gold, platinum, or any other metal or alloy, or polymers or composites, having sufficient

biocompatibility, rigidity, flexibility, radial strength, radiopacity and antithrombogenicity.

Although the connecting members 48 have been described above as having the same material as the struts 42, 44, it is possible to provide the connecting members 48 with a different material without departing from the spirit and scope of the present invention. Such a material should be springy in nature and should allow the connecting members 48 to be compressed and expanded in the longitudinal direction to compensate for the foreshortening experienced by the struts 42 and 44. Non-limiting examples of such materials can include any of the materials described above for the stent 40.

2. Methods of Manufacture

The stent 40 can be made from one of a number of methods, depending on the material of the stent 40 and the desired nature of deployment.

In a non-limiting first preferred method, the stent 40 is fabricated from a solid Nitinol tube with dimensions that are identical to the stent 40 when it is in the fully compressed state. The pattern of the stent 40 (i.e., its struts 42, 44 and connecting members 48) is programmed into a computer-guided laser cutter or lathe which cuts out the segments between the struts 42, 44 and the connecting members 48 in a manner which closely controls the outside diameter and wall thickness of the stent 40.

After the cutting step, the stent 40 is progressively expanded until it reaches its fully expanded state. The expansion can be performed by an internal expansion fixture, although other expansion apparatus and methods can be used without departing from the spirit and scope of the present invention. The overall length of the stent 40 must be consistently maintained throughout the expansion of the stent 40 from its fully compressed to its fully expanded states.

Once the stent 40 has been expanded to its fully expanded state, it is heat-treated to "set" the shape memory of the

Nitinol material to the fully expanded dimensions. The stent 40 is then cleaned and electro-polished.

The next step is to compress the stent 40 again into a dimension which allows for delivery into a vessel, either through percutaneous delivery or through minimally invasive surgical procedures. Specifically, the stent 40 must be compressed into a smaller state so that it can be delivered by a delivery device to the desired location of the vessel. Any conventional delivery device could be used, such as but not limited to a tube, catheter, or sheath. This compression is accomplished by cooling the stent 40 to a low temperature, for example, zero degrees Celcius, and while maintaining this temperature, compressing the stent 40 to allow the stent 40 to be inserted inside the delivery device. Once inserted inside the delivery device, the stent 40 is held by the delivery device in the compressed state at room temperature.

In a non-limiting second preferred method, a balloon-expandable stent 40 can be fabricated by connecting a plurality of wires that have been bent or formed into the desired shapes for the struts 42, 44 and connecting members 48. The connection can be accomplished by welding, tying, bonding, or any other conventional method. Alternatively, wire electro-discharge machining can be used. The wires are capable of experiencing plastic deformation when the stent 40 is compressed, and when the stent 40 is expanded. Upon plastic deformation of the stent 40 to either the compressed or the expanded state, the stent 40 remains in this state until another force is applied to plastically deform the stent 40 again.

While certain methods of manufacture have been described above, it will be appreciated by those skilled in the art that other methods of manufacture can be utilized without departing from the spirit and scope of the present invention.

3. <u>Deployment Methods</u>

The stent 40 can be deployed by a number of delivery systems and delivery methods. These delivery systems and methods will vary depending on whether the stent 40 is expanded by self-expansion, radial expansion forces, or radio frequency.

While the description above refers to particular embodiments of the present invention, it will be understood that many modifications may be made without departing from the spirit thereof. The accompanying claims are intended to cover such modifications as would fall within the true scope and spirit of the present invention.

What is claimed is:

1. A stent comprising:

a plurality of annular elements, each annular element having a compressed state and an expanded state, wherein each annular element has a longitudinal dimension which is smaller in the expanded state than in the compressed state; and

at least one connecting member connecting adjacent annular elements, the connecting member operating to compensate for the smaller longitudinal dimension of the annular elements in the expanded state.

2. The stent of claim 1, wherein each annular element comprises a plurality of alternating struts and apices connected to each other to form a substantially annular configuration.

3. The stent of claim 2, wherein the connecting members are connected to the apices of the adjacent annular members.

4. The stent of claim 2, wherein the plurality of struts comprises left and right struts, with each pair of left and right struts connected to each other at an apex.

5. The stent of claim 2, wherein each strut has a longitudinal dimensional which is smaller when the annular elements are in the expanded state than in the compressed state.

6. The stent of claim 2, wherein each strut has a longitudinal dimensional which is larger when the annular elements are in the compressed state than in the expanded state.

7. The stent of claim 1, wherein the connecting member has a plurality of alternating segments.

8. The stent of claim 7, wherein the connecting member has a plurality of alternating curved segments defining alternating top and bottom curved apices.

9. The stent of claim 8, wherein the plurality of alternating curved segments have a higher amplitude and a smaller wavelength than when the annular elements are in the compressed state.

10. The stent of claim 7, wherein the connecting member has a plurality of alternating curved and straight segments.

11. The stent of claim 7, wherein the connecting member has a plurality of alternating and angled straight segments.

12. The stent of claim 1, wherein the connecting member has a larger longitudinal dimension when each annular element is in the expanded state than in the compressed state to compensate for the smaller longitudinal dimension of the annular element in the expanded state.

13. The stent of claim 1, wherein the connecting member has a smaller longitudinal dimension when each annular element is in the compressed state than in the expanded state to compensate for the larger longitudinal dimension of the annular element in the compressed state.

14. The stent of claim 1, wherein the stent is made from a shape memory alloy.

15. The stent of claim 14, wherein the shape memory alloy is Nitinol.

16. The stent of claim 1, wherein the stent has a plurality of segments along its length, each segment assuming a different diameter when the stent is in its expanded state.

17. The stent of claim 16, wherein the stent has a tapered configuration in which the diameter of the stent gradually changes from one segment to another segment.

18. The stent of claim 16, wherein the stent has a stepped configuration in which the diameter of the stent transitions abruptly from one segment to another segment.

19. The stent of claim 2, wherein at least one of the annular elements is closed such that the plurality of alternating struts and apices are connected to each other to form a closed annular element.

20. The stent of claim 19, wherein at least one of the annular elements are open such that the plurality of alternating struts and apices are not connected at at least one location.

21. The stent of claim 1, further in combination with a biocompatible graft covering.

22. A stent having a plurality of segments along its length and comprising:

a plurality of annular elements, each annular element having a compressed state and an expanded state;

at least one connecting member connecting adjacent annular elements; and

a plurality of apertures defined by adjacent annular elements and connecting members;

wherein the apertures of different stent segments have different sizes.

23. The stent of claim 22, wherein each annular element comprises a plurality of alternating struts and apices connected to each other to form a substantially annular configuration, and wherein the connecting members are connected to the apices of the adjacent annular members, with the apertures defined by the adjacent struts and connecting members.

24. The stent of claim 22, wherein each segment of the stent assumes a different diameter when the stent is in its expanded state.

25. The stent of claim 24, wherein the stent has a tapered configuration in which the diameter of the stent gradually changes from one segment to another segment.

26. The stent of claim 24, wherein the stent has a stepped configuration in which the diameter of the stent transitions abruptly from one segment to another segment.

27. A stent having a plurality of segments and comprising:

a plurality of annular elements, each annular element having a compressed state and an expanded state;

at least one connecting member connecting adjacent annular elements; and

means for providing two of the plurality of segments of the stent with different degrees of flexibility.

28. The stent of claim 27, wherein the means for providing two of the plurality of segments of the stent with different degrees of flexibility comprises a plurality of gaps formed by omitting at least one of the connecting members between adjacent annular elements.

29. The stent of claim 27, wherein each annular element comprises a plurality of alternating struts and apices connected to each other to form a substantially annular configuration, and wherein the connecting members are connected to the apices of the adjacent annular members.

30. The stent of claim 29, wherein the means for providing two of the plurality of segments of the stent with different degrees of flexibility comprises a plurality of gaps formed by omitting at least one of the struts.

31. The stent of claim 30, wherein the plurality of gaps is further formed by omitting at least one of the connecting members between adjacent annular elements.

32. The stent of claim 27, further comprising a plurality of apertures defined by adjacent annular elements and connecting members, and wherein the means for providing two of the plurality of segments of the stent with different degrees of flexibility comprises providing the apertures of different stent segments with different sizes.

ABSTRACT OF THE DISCLOSURE

An intraluminal prosthesis is provided with a plurality of annular elements. Each annular element includes a plurality of struts and apices connected to form an annular configuration. Each annular element has a compressed state and an expanded state, and has a longitudinal dimension which is smaller in the expanded state than in the compressed state. A plurality of connecting members connect the apices of adjacent annular elements. The connecting members have a plurality of alternating segments that function to compensate for the smaller longitudinal dimension of each annular element in the expanded state. The stent may be provided with varying flexibility along its length and/or circumference, and may include segments that have different diameters.

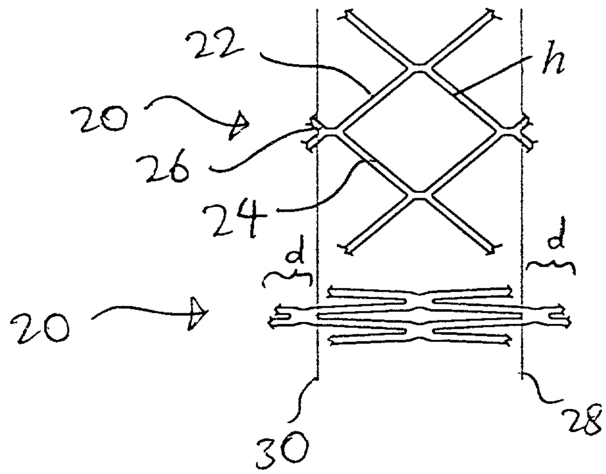
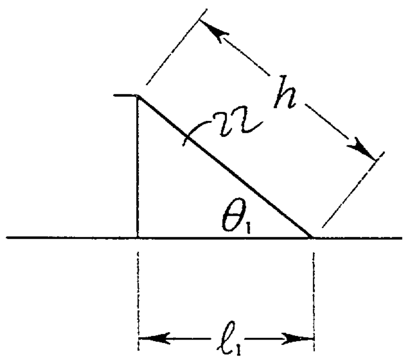


FIG. 1A

FIG. 1B

PRIOR ART

FIG. 2A



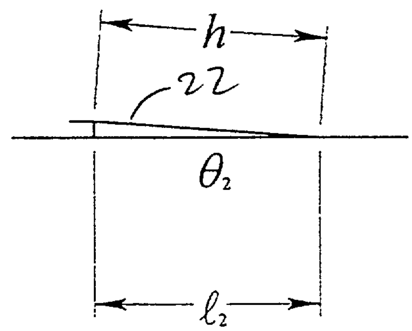


FIG. 2B

Expanded

$$\ell_1 = h\cos\theta_1$$

Compressed

$$\ell_2 = h\cos\theta_2$$

$$\Delta\ell = h(\cos\theta_2 - \cos\theta_1)$$

PRIOR ART

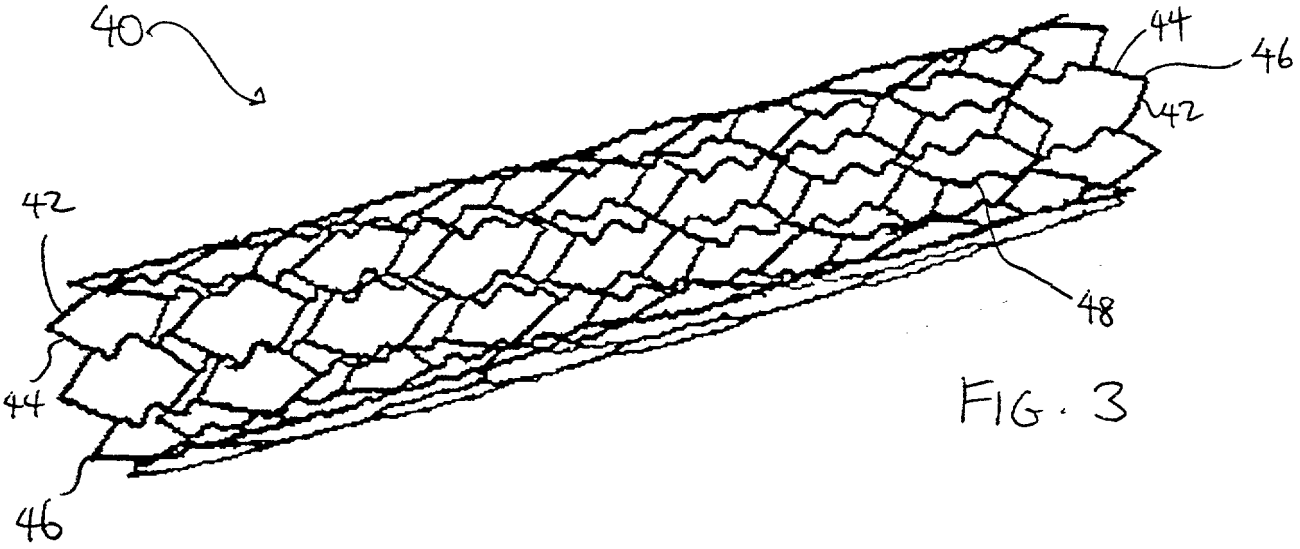


FIG. 3

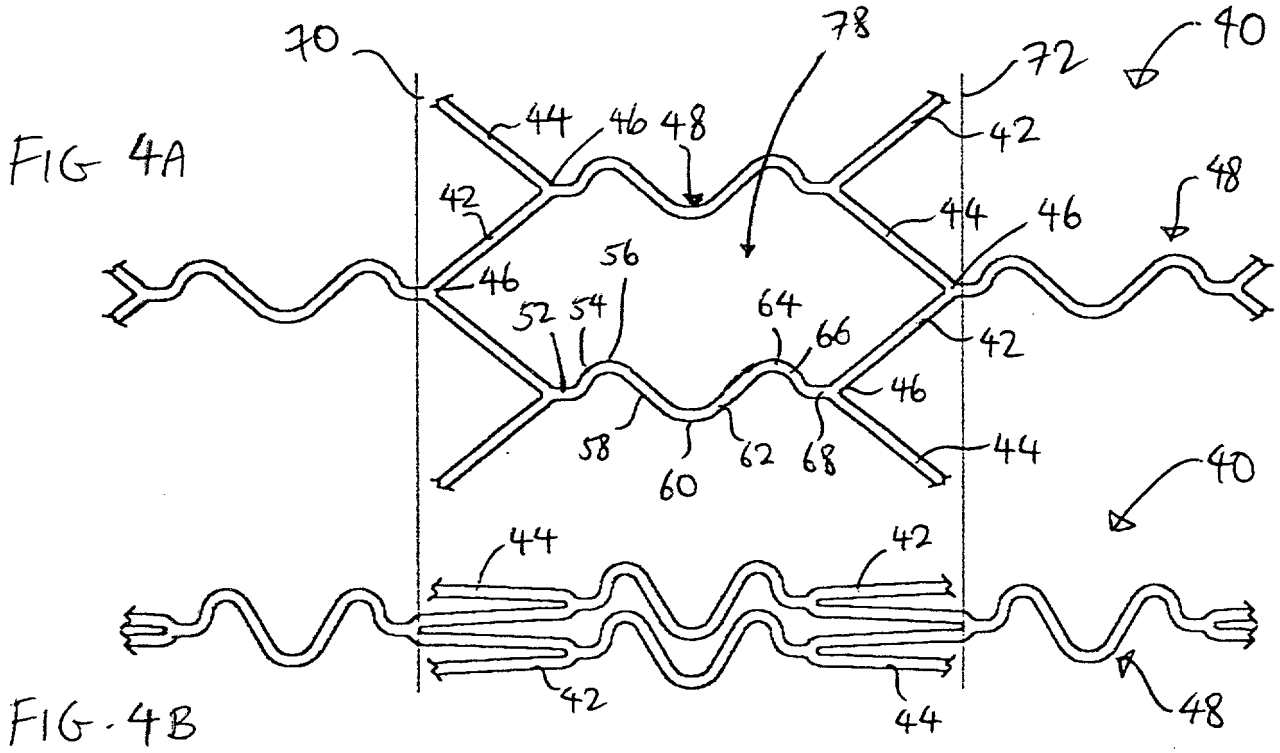


FIG 4A

FIG. 4B

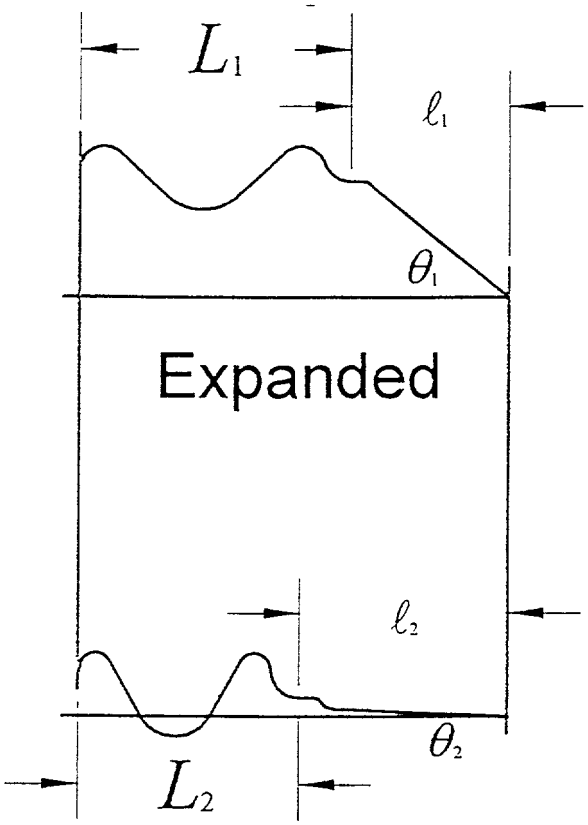


FIG. 5A

FIG 5B

$$\ell_2 - \ell_1 = L_1 - L_2$$

FIG. 6A

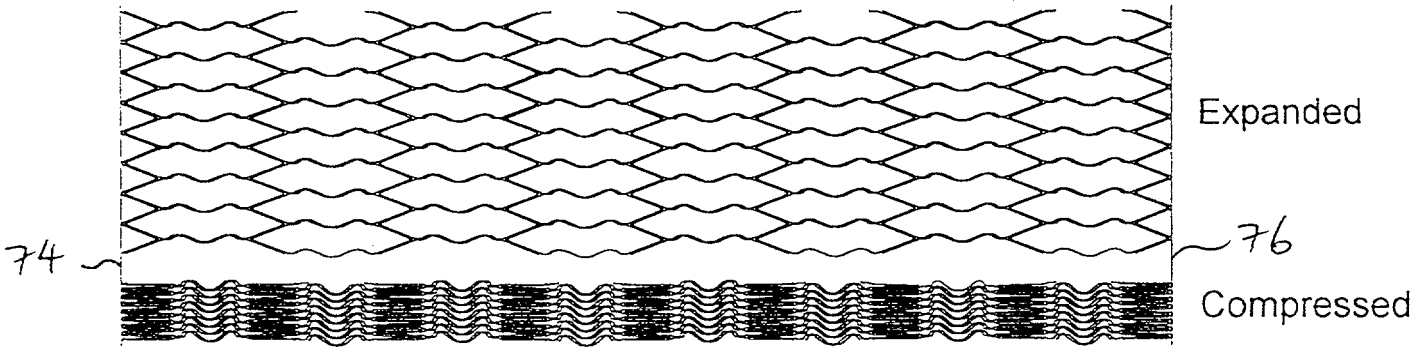


FIG. 6B

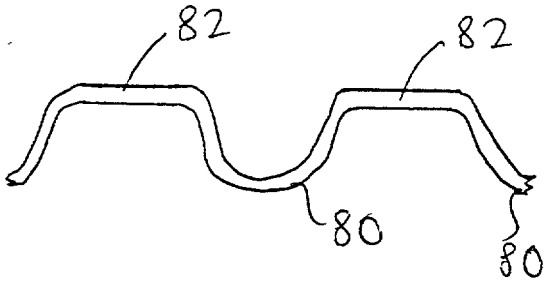


FIG. 7.

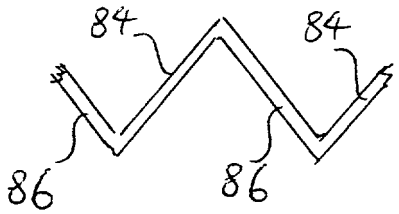


FIG. 8

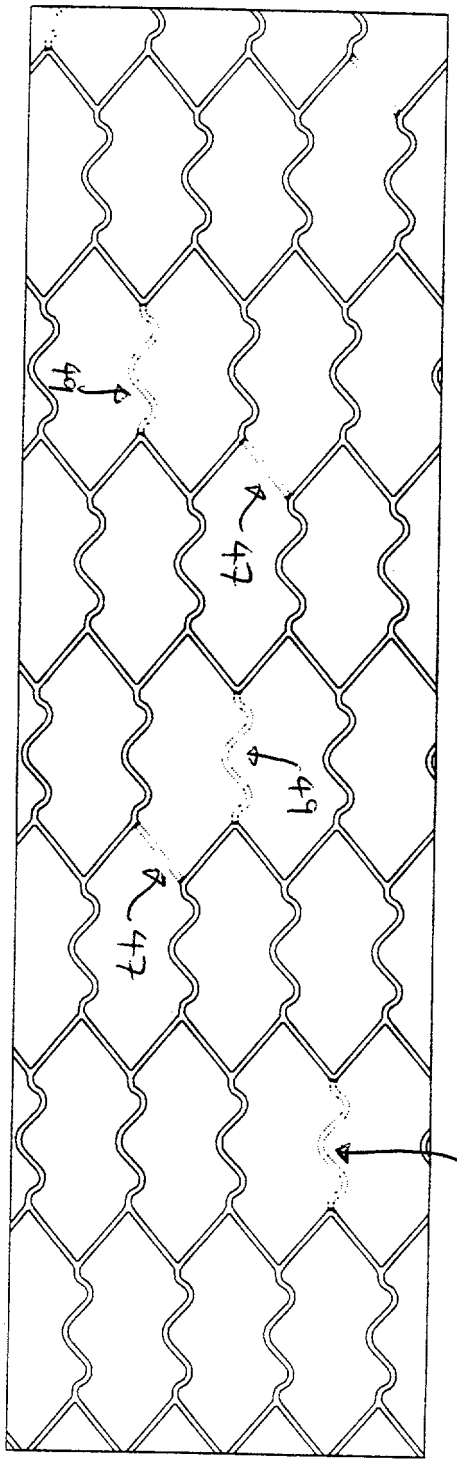


FIG 9

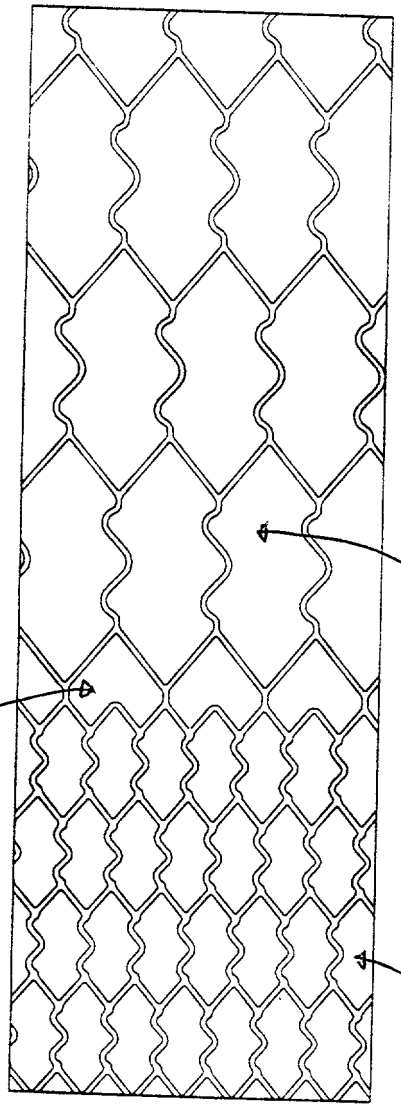


FIG. 10

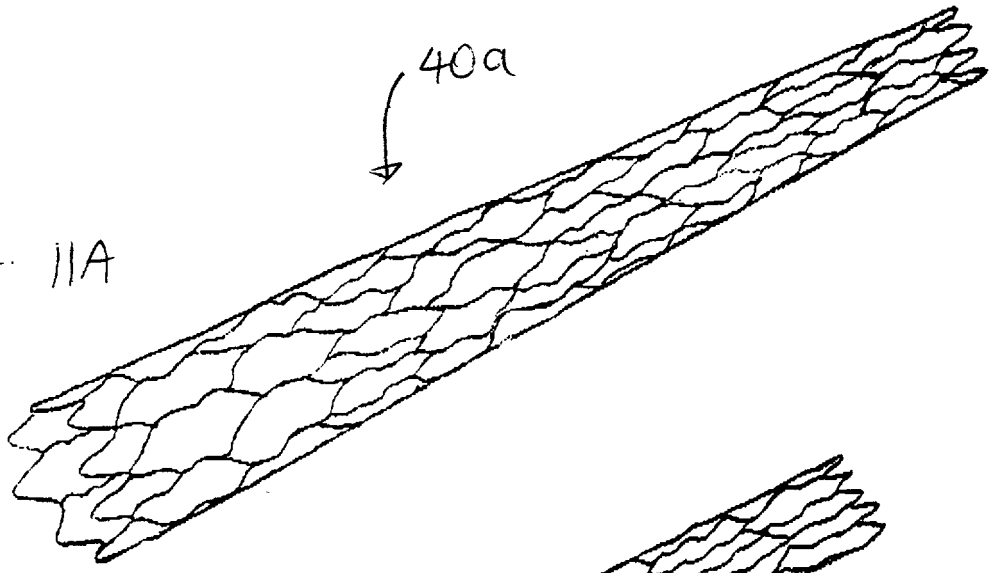


FIG. 11A

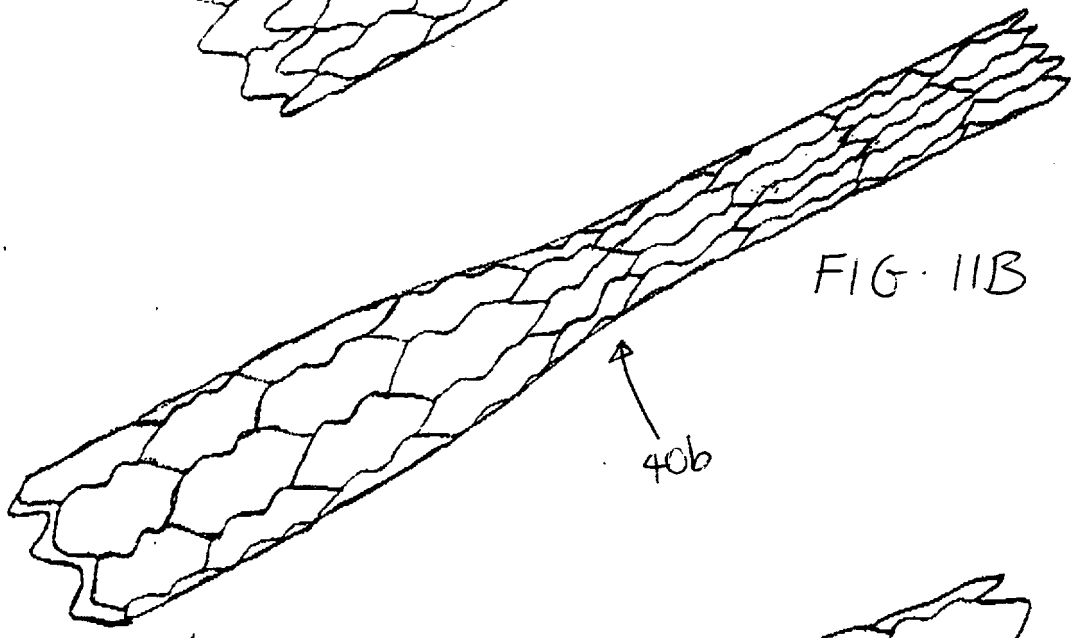


FIG. 11B

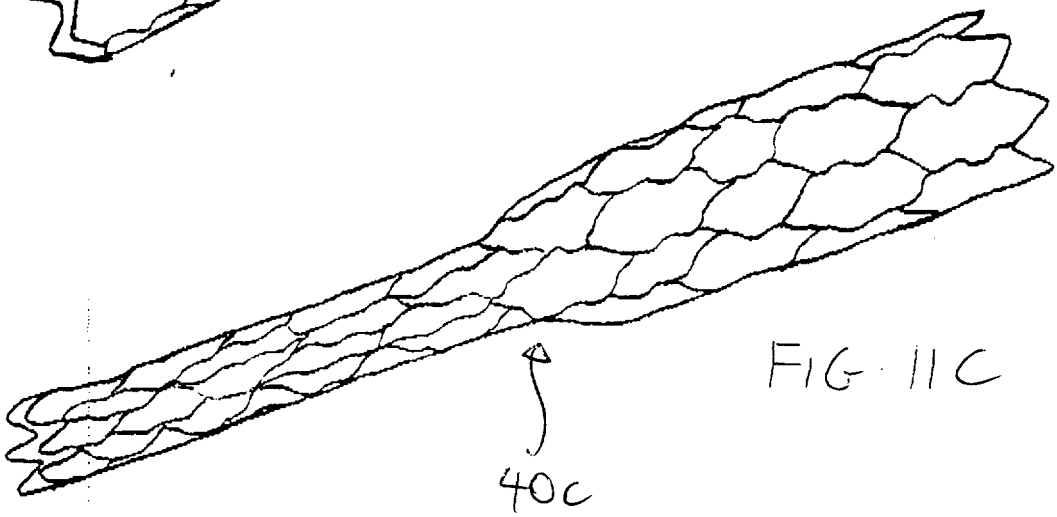


FIG. 11C

Docket No.: PAT-1129

DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that the information below is true, that I believe that I am the original, first and sole inventor if only one name is listed below, or a joint inventor if plural inventors are named below, of the invention entitled NON-FORESHORTENING INTRALUMINAL STENT, which is described and disclosed in:

( ) the attached specification, or
(X) the specification in Application Serial No. 08/797,814, filed February 7, 1997, or
( ) as amended on _____,

and for which a patent is sought, and that my residence, post office address and citizenship are as stated below next to my name.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, Section 1.56(a).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by the amendment referred to above (if any).

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119 of the following foreign application listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application:			Priority Claimed
Country	Appl. No.	Filing Date	Yes / No
_____	_____	_____	

I hereby claim the benefit under Title 35, United States Code, Section 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application are not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, Section 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, Section 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

Application Serial No.	Filing Date	Status

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

POWER OF ATTORNEY: As the named inventor, I hereby appoint the following attorney(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith:

RAYMOND SUN, Reg. No. 35,699

Send all correspondence to:

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12420 Woodhall Way
Tustin, California 92782
Tel: 714-544-2819

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Inventor's signature: G Roubin

Date: 4/8/97

Residence: Birmingham, Alabama

Citizenship: AUSTRALIAN

Post Office Address: 2007 River Lakes Drive, Birmingham, AL 35244

please fill in the citizenship.

Full name of inventor 2: Geoffrey Hamilton White

Inventor's signature: G.H. White

Date: 5/15/97

Residence: Sydney, Australia

Citizenship: Australian

Post Office Address: 22 Nicholson Street, Balmain East, Sydney, N.S.W. 2041, Australia

Full name of inventor 3: Sriram S. Iyer

Inventor's signature: [signature]

Date: 4/14/97

Residence: Birmingham, Alabama

Citizenship: INDIAN

Please fill in the citizenship.

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Full name of inventor 4: Russell J. Redmond

Inventor's signature: [signature]

Date: 4-23-97

Residence: Goleta, California

Citizenship: U.S.A.

Post Office Address: 1148 North Fairview Avenue, Goleta, CA 93117

Full name of inventor 5: Claude A. Vidal

Inventor's signature: Claude A. Vidal

Date: 4.23.97

Residence: Santa Barbara, California

Citizenship: U.S.A.

Post Office Address: 5426 San Patricio Drive, Santa Barbara, CA 93111

Docket: PAT-1129

Applicant or Patentee: Gary S. Roubin, Geoffrey H. White, Sriram S. Iyer, Russell J. Redmond, Claude A. Vidal
Serial No: 08/797,814
Filing Date: February 7, 1997
For: NON-FORESHORTENING INTRALUMINAL PROSTHESIS

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) and 1.27(b)) -- SMALL BUSINESS CONCERN

I hereby declare that I am an official of the small business concern empowered to act on behalf of the concern identified below.

NAME OF CONCERN: Cornerstone Devices, Inc.
ADDRESS OF CONCERN: 4001 Calle Juno, San Clemente, CA 92673

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention entitled Non-Foreshortening Intraluminal Prosthesis by Gary S. Roubin, Geoffrey H. White, Sriram S. Iyer, Russell J. Redmond, and Claude A. Vidal described in:

( ) the specification filed herewith.
(X) Appl. Serial No. 08/797,814, filed February 7, 1997
( ) U.S. Patent No. _____, issued _____.

If the right held by the above-identified small business concern is not exclusive, each individual, concern or organization having rights to the invention is listed below and no rights to the invention are held by any person, other than the inventor, who could not qualify as a small business concern under 37 CFR 1.9(d) or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

(X) No such person, concern or organization
( ) Persons, concerns or organizations listed below:

FULL NAME: _____
ADDRESS: _____
( ) Individual ( ) Small Business Concern

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time

of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate (37 CFR 1.28(b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING: Alan J. Schempp

TITLE OF PERSON SIGNING: President

ADDRESS: 4001 Calle Juno, San Clemente, CA 92673

SIGNATURE: Date: 4/1/97